Tab 21 PREMARKET NOTIFICATION 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Manufacturer:

SonoScape Company Limited

Address: 4/F., Yizhe Building, Yuquan Road, Nanshan, Shenzhen 518051,

P.R.China

Tel: (86) 755-26722890

Fax: (86) 755-26722850

Contact Person: Zhiqiang Chen

Name of the device:

* Trade/Proprietary Name:

SSI-8000 Mobile Digital Color Doppler Ultrasound System

* Common Name: Diagnostic Ultrasound System and Transducers

* Classification:

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

Legally Marketed Predicate Device:

Mindray DC-7 Diagnostic Ultrasound System and Transducers – K092691
SonoScape SSI-5000 Diagnostic Ultrasound System and Transducer – K052042
SonoScape S8 Diagnostic Ultrasound System and Transducer – K092922

Device Description:

The SonoScape SSI-8000 ultrasound system is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 3D/4D.

Intended Use:

The device device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Trans-esoph (Cardiac), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn.

Safety Considerations:

The SSI-8000 Diagnostic Ultrasound System with added transducer incorporates the same fundamental technology as the predicate device. The device has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued September 9, 2008. The acoustic output is measured and calculated per NEMA UD 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37, ISO 10993-5 and ISO 10993-10.

Conclusion:

The conclusions drawn from testing of the SSI-8000 Diagnostic Ultrasound System with added transducer demonstrate that the device is as safe and effective as the legally marketed predicate devices.



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

SONOSCAPE COMPANY LIMITED % Ms. Min Yao Official Correspondent SonoScape America 30251 Cedarbrook Road HAYWARD CA 94544

MAR - 4 2011

Re: K102642

Trade/Device Name: SSI-8000 Mobil Digital Color Doppler Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: February 14, 2011 Received: February 16, 2011

Dear Ms. Yao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SSI-8000 Mobil Digital Color Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

2P1 Phased Array
5P1 Phased Array
6V1 Micro-curved Array
6V3 Micro-curved Array
C611 Micro-curved Array
C362 Curved Array
C344 Curved Array

VC6-2 Curved Array
L743 Linear Array
L741 Linear Array
L742 Linear Array
MPTEE Multi-plane Array
MPTEE mini Milti-plane Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6898.

Sincerely Yours,

Mary Pastel, ScD.

Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)

Tab 3 Indications For Use

510(k)	Number ((if known)
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Device Name:

SSI-8000 Mobil Digital Color Doppler Ultrasound System

Indications for Use:

The SonoScape SSI-8000 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Trans-esoph (Cardiac), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use _____(21 CFR 807 Subpart C)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

System:

Sonoscape SSI-8000

Diagnostic Ultrasound Pulsed Echo System

Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application			******		Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	N	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging&	Fetal	N	И	N		N	N	Note 1	Notes 2,4,5
Other	Abdominal	N	N	N		N	N	Note 1	Notes 2,4,5
	Intra-operative Specify Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic	N	Z	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral			_					
	Trans-esoph.(non-Card)							,	
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular	T							
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4,5
<u> </u>	Other (Urology)	N	N	N		N	N	Note 1	Notes 2, 4
Cardiac	Cardiac Adult	Ñ	N	N	N	N	N	Note 1	Notes 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intra-cardiac	\perp							
	Other (specify)					•			
Peripheral	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
Vessel	Other (specify)								

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102642

Transducer: 2P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic			•					
Fetal Imaging&	Fetal								
Other	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify							· · ·	
	Intra-operative Neuro	1							1
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	1			<u> </u>				
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Trans-rectal								, , , , , ,
	Trans-vaginal								
	Trans-urethral	1							
	Trans-esoph.(non-Card)	 							
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)			•					
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								-
Cardiac	Cardiac Adult	N	Ň	N	N	N	N	Note 1	Notes 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)		L	<u>-</u> -	<u> </u>				
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	1			<u> </u>			<u></u>	
Vessel	Other (specify)				1]

N = new indication;	P = previously cleared by FDA;		E = added under this append
Note 1: Other Combined includes: B	/M; B/PWD; B/THI (The feati	ire does not use co	ntrast agents); M/Color M; B/Color
Doppler; B/Color Doppler.	/PWD; B/Power Doppler/PWI)	
Note 2: Tissue Harmonic Imaging	Note 3: TDI	Note 4: 3D	Note 5: 4D
Note 6: Small Organ: breast, thyroid	, testes		
		•	
Prescription UseX	AND/OR		Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			 (21 CFR 807 Subpart C)
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Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: 5P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application	Ì				Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								i
Fetal Imaging&	Fetal						-		
Other	Abdominal								
	Intra-operative Specify								· · · · · · · · · · · · · · · · · · ·
	Intra-operative Neuro								- : -
	Laparoscopic					, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal							· · · · · · · · · · · · · · · · · · ·	
	Trans-urethral	<u> </u>							<u> </u>
-	Trans-esoph.(non-Card)	_					· · -		· · · · · · · · · · · · · · · · · · ·
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	$oxed{oxed}$							
Vessel	Other (specify)								

	Intravascular(Cardiac)]			1	
	Trans-esoph.(Cardiac)						
	Intra-cardiac						
	Other (specify)						
Peripheral	Peripheral vessel						
Vessel	Other (specify)						
N = new indicat	ion; P=p	reviously cleare	ed by FDA;		E =	added under this	appendix
Note 1: Other	Combined includes: B/M;	B/PWD; B/7	THI (The feat	ure does not use co	ontrast agents); N	A/Color M; B/C	Color
Doj	ppler; B/Color Doppler/PW	D; B/Power	Doppler/PWI	D			
Note 2: Tissu	e Harmonic Imaging	No	ote 3: TDI	Note 4: 3D		Note 5: 4D	
Note 6: Small	l Organ: breast, thyroid, tes	tes					
Prescription (Use X		AND/OR		Over-The-C	Counter Use	
(Part 21 CFR	801 Subpart D)				(21 CF	FR 807 Subpart	C)
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Transducer: 6V1 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation										
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify				
Ophthalmic	Ophthalmic	$\neg \neg$											
Fetal Imaging&	Fetal						.						
Other	Abdominal								1				
	Intra-operative Specify						· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · ·					
	Intra-operative Neuro	\top				****							
	Laparoscopic												
	Pediatric												
	Small Organ (specify)								-				
	Neonatal Cephalic	1					- <u>-</u>						
	Adult Cephalic												
	Trans-rectal	l N	N	N		Ñ	N	Note 1	Notes 2,4				
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4				
	Trans-urethral					.,		11010 1	110103 2,4				
	Trans-esoph.(non-Card)												
	Musculo-skeletat (Conventional)						-		<u> </u>				
	Musculo-skeletal (Superficial)			-									
	Intravascular												
	Other (Ob/GYN)												
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2, 4				
Cardiac	Cardiac Adult												
	Cardiac Pediatric												
	Intravascular(Cardiac)												
	Trans-esoph.(Cardiac)												
•	Intra-cardiac												
	Other (specify)												
Peripheral	Peripheral vessel												
Vessel	Other (specify)								<u> </u>				

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N = new indication	a;		P = previou	asly c	leare	d by FDA;		-	E	= added under	r this appendi
Note 1: Other C	Combine	d includes:	B/M; B/P	WD;	B/T	HI (The	feature d	oes not use co	ontrast agents); l	M/Color M	B/Color
		olor Dopple							3 /.	•	,
Note 2: Tissue 1	Harmon	ic Imaging			No	te 3: TDI	3	Note 4: 3D		Note 5:	4D
Note 6: Small C	Organ: b	reast, thyro	id, testes								
.	•	-				43 TD /0	_				
Prescription Us	eX					AND/O	R			Counter Use	
(Part 21 CFR 80	01 Subp	art D)							(21 C	FR 807 Sub	part C)
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Transducer: 6V3 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clin	ical Application	T			•	Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic .	Ophthalmic								
Fetal Imaging&	Fetal								
Other	Abdominal								
	Intra-operative Specify	1							
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric					- 			ţ
	Small Organ (specify)								
	Neonatal Cephalic					•			
	Adult Cephalic			- "					
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular	1	1						
	Other (Ob/GYN)								
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2, 4
Cardiac	Cardiac Adult	J	<u> </u>		l				
	Cardiac Pediatric			[
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)					i			
	Intra-cardiac						<u> </u>		
	Other (specify)						ļ		
Peripheral	Peripheral vessel					<u> </u>			<u> </u>
Vessel	Other (specify)				<u> </u>	<u> </u>		<u> </u>	<u>L</u>

N = new indication;	P = previously cleared by FDA;	$\mathbf{E} = \mathbf{added}$ under this appendix
Note 1: Other Combined i	ncludes: B/M; B/PWD; B/THI (The feature does not use	contrast agents); M/Color M; B/Color
Doppler; B/Colo	or Doppler/PWD; B/Power Doppler/PWD	
Note 2: Tissue Harmonic		Note 5: 4D
Note 6: Small Organ: brea		
Prescription Use X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart		(21 CFR 807 Subpart C)
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Transducer: C611 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinic	al Application	Mode of Operation									
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify		
Ophthalmic	Ophthalmic										
Fetal	Fetal										
Imaging&		<u> </u>						<u></u>			
Other	Abdominal	N	N	N		N	N	Note 1	Notes 2,4		
	Intra-operative Specify										
	Intra-operative Neuro										
	Laparoscopic	ļ									
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4		
	Small Organ (specify)	<u> </u>	j								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4		
	Adult Cephalic							·			
-	Trans-rectal										
	Trans-vaginal								<u> </u>		
	Trans-urethral										
	Trans-esoph.(non-Card)					· · · · · · · · · · · · · · · · · · ·					
	Musculo-skeletal (Conventional)		,								
	Musculo-skeletal (Superficial)						•				
	Intravascular										
	Other (Ob/GYN)										
	Other (Urology)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4		
	Intravascular(Cardiac)										
	Trans-esoph.(Cardiac)										
	Intra-cardiac										
	Other (specify)										
Peripheral	Peripheral vessel	l									
Vessel	Other (specify)										
N = new indication;	P = previo	usly e	cleare	d by FDA;			E	= added under this	appendix		
Note 1: Other Co	mbined includes: B/M; B/P	_		•		oes not use co					
	er; B/Color Doppler/PWD; I						<i>5</i>	,			
Note 2: Tissue H				te 3: TDI		Note 4: 3D		Note 5: 4D			
	can breast theraid testes										

Doppler; B/Color Doppler/PWD; B/Note 2: Tissue Harmonic Imaging	,		Note 5: 4D
Note 6: Small Organ: breast, thyroid, testes			
Prescription UseX	AND/OR		Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)
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Indications For Use

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Office of In Vitro Diagnóstic Device Evaluation and Safety

Transducer: C362 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	N	N	Ν		N	N	Note 1	Notes 2,4
Other	Abdominal	N	Ν	N		N	N	Note1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)						······································		
	Neonatal Cephalic	1		•		· · · · · · · · · · · · · · · · · · ·			
	Adult Cephalic							<u> </u>	
	Trans-rectal								 -
	Trans-vaginal								·
	Trans-urethral	<u> </u>							·
	Trans-esoph.(non-Card)	<u> </u>							
	Musculo-skeletal	-				· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·		
	(Conventional)				,				
	Musculo-skeletal (Superficial)								
	Intravascular	\top				· · · · · · · · · · · · · · · · · · ·	······································		
	Other (Ob/GYN)	N	N	N		N	N	Note1	Notes 2 4
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2, 4
Cardiac	Cardiac Adult								· · · · · · · · · · · · · · · · · · ·
	Cardiac Pediatric								
	Intravascular(Cardiac)						· · · · · · · · · · · · · · · · · · ·		
	Trans-esoph.(Cardiac)								
	Intra-cardiac	1.							
	Other (specify)								"
Peripheral	Peripheral vessel								
Vessel	Other (specify)						· · · · · · · · · · · · · · · · · · ·		

N = new indication;	$P = previously cleared by FDA;$ E $\stackrel{.}{=}$ added under this									
Note 1: Other Combined inc	cludes: B/M; B/PWD; B/THI (The featur	e does not use contrast	agents); M/Color M; B/Color							
	Doppler/PWD; B/Power Doppler/PWD	•	,							
Note 2: Tissue Harmonic In	naging Note 3: TDI	Note 4: 3D	Note 5: 4D							
Note 6: Small Organ: breast	, thyroid, testes									
Prescription Use X	AND/OR	c	over-The-Counter Use							
(Part 21 CFR 801 Subpart D))		(21 CFR 807 Subpart C)							
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Office of In Vitro Diagnostic Device Evaluation and Safety

Indications For Use

Transducer: C344 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	cal Application		Mode of Operation									
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify			
Ophthalmic	Ophthalmic											
Fetal Imaging&	Fetal	N	N	N		N	N	Note 1	Notes 2, 4			
Other	Abdominal	N	N	N		N	N	Note 1	Notes 2, 4			
	Intra-operative Specify	1						11010 1	140163 2, 4			
	Intra-operative Neuro					·						
	Laparoscopic											
	Pediatric											
	Small Organ (specify)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal								·			
	Trans-urethral											
	Trans-esoph.(non-Card)				,			 				
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)							· · · · · · · · · · · · · · · · · · ·				
	Intravascular								···			
	Other (Ob/GYN)	N	Ν	N		N	N	Note 1	Notes 2, 4			
	Other (Urology)	N	Ν	N		N	N	Note 1	Notes 2, 4			
Cardiac	Cardiac Adult											
	Cardiac Pediatric											
	Intravascular(Cardiac)											
	Trans-esoph.(Cardiac)											
	Intra-cardiac											
	Other (specify)								····			
Peripheral	Peripheral vessel								······································			
Vessel	Other (specify)							·····				

N = new indication;	P = previously cleared by FDA;	E = added under this append
Doppler; B/Color 1	Doppler/PWD; B/Power Doppler/PWD	not use contrast agents); M/Color M; B/Color
Note 2: Tissue Harmonic Im Note 6: Small Organ: breast,		e 4: 3D Note 5: 4D
Prescription Use X (Part 21 CFR 801 Subpart D	AND/OR	Over-The-Counter Use(21 CFR 807 Subpart C)
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications For Use

Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinic	eal Application	Mode of Operation									
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify		
Ophthalmic	Ophthalmic										
Fetal Imaging &	Fetal	N	N	N		N	N	Note 1	Notes 2,4,5		
Other	Abdominal	N	N	N		N	N	Note 1	Notes 2,4,5		
	Intra-operative Specify								110100 2, 1,0		
	Intra-operative Neuro						\ 				
	Laparoscopic										
	Pediatric	L							<u> </u>		
	Small Organ (specify)							 			
	Neonatal Cephalic						·-··				
	Adult Cephalic	 									
	Trans-rectal							 			
	Trans-vaginal	 		· · · · · · ·							
	Trans-urethral								· · · · · · · · · · · · · · · · · · ·		
	Trans-esoph.(non-Card)	 							 		
	Musculo-skeletal (Conventional)						· · · · · · · · · · · · · · · · · · ·				
	Musculo-skeletal (Superficial)						•	·	·		
	intravascular						- · ,				
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4,5		
	Other (Urology)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intravascular(Cardiac)							· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·		
	Trans-esoph.(Cardiac)										
	Intra-cardiac							<u> </u>			
	Other (specify)										
Peripheral	Peripheral vessel										
Vessel	Other (specify)								· · · · · · · · · · · · · · · · · · ·		
N = new indication:	P = previo	nslv c	les rec	hv FDA			F	= added under this	ennandiy		

V C33C1	Other (specify)			_L		1	1	1	
N = new indication;		P = previous	ly clear	ed by FDA	;		E	= added under ti	is append
Note 1: Other Cor	nbined includes:	B/M; B/PW	'D; B/	THI (The	feature	does not use co	ontrast agents);	M/Color M; B	/Color
Doppler	; B/Color Dopple	эг/PWD; B/I	Power	Doppler/	PWD				
Note 2: Tissue Ha	rmonic Imaging		No	ote 3: TD	1	Note 4: 3D		Note 5: 41)
Note 6: Small Org	an: breast, thyroi	d, testes							
	-								
Prescription Use	X			AND/C)R		Over-The-	Counter Use	
(Part 21 CFR 801	Subpart D)						(21 C	FR 807 Subpa	rt C)
	•	•					`	•	
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: L743 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application General Specific			Mode of Operation									
Specific FRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify				
almic								 				
ninal		Ī.,										
perative Specify								<u> </u>				
perative Neuro												
oscopic												
ric												
Organ (specify)	N	N	N		N	N	Note 1	Notes 2, 4				
al Cephalic						 -						
Cephalic					 							
rectal	 					·	 	 				
vaginal												
urethral	1-											
esoph.(non-Card)	1							 				
ilo-skeletal entional)	N	N	N		N	N	Note 1	Notes 2, 4				
ilo-skeletal rficial)	N	N	N		N	N	Note 1	Notes 2, 4				
scular								· · · · · · · · · · · · · · · · · · ·				
(Ob/GYN)												
(Urology)												
c Adult												
c Pediatric												
scular(Cardiac)												
esoph.(Cardiac)												
ardiac							<u> </u>					
(specify)								<u> </u>				
eral vessel	N	N	N		N	N	Note 1	Notes 2, 4				
(specify)]										
(s	pecify) ral vessel pecify)	pecify) ral vessel N pecify)	pecify) ral vessel N N pecify)	pecify) ral vessel N N N	pecify) ral vessel N N N pecify)	pecify) N N N ral vessel N N N N pecify) N N N N	pecify) N N N N ral vessel N N N N N pecify) N	pecify) N N N N N N N				

vessei	Other (specify)			1 1				ì
N = new indication	;	P = previou	isly cleare	d by FDA;		E	= added under thi	s append
Note 1: Other C	ombined includes:	B/M; B/PV	WD; B/T	HI (The feat	ure does not use c	ontrast agents);	M/Color M; B/	Color
	er; B/Color Doppl					• //		
Note 2: Tissue I	Harmonic Imaging		No	te 3: TDI	Note 4: 3D		Note 5: 4D	J
Note 6: Small O	rgan: breast, thyro	id, testes						
Dungaintian I In-	v			AND/OD		0 771	~	
Prescription Use				AND/OR			Counter Use	
(Part 21 CFR 80	11 Subpart D)					(21 C	FR 807 Subpart	î C)
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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 4102642

Transducer: L741 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application General Specific			Mode of Operation										
Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude)	Other* Combined	Other* Specify					
Ophthalmic							 	 					
Fetal					-								
Abdominal						·····							
Intra-operative Specify	1												
Intra-operative Neuro					·								
Laparoscopic					-								
Pediatric													
Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2, 4					
				_		- · · · · · · · · · · · · · · · · · · ·		Trotos 2, 4					
								 					
Trans-rectal	 						<u> </u>						
Trans-vaginal													
Trans-urethral	 					· · · · · · · · · · · · · · · · · · ·	<u></u>						
Trans-esoph (non-Card)	1				·	<u> </u>		<u> </u>					
Musculo-skeletal	N	N	N	-	N	N	Note 1	Notes 2, 4					
Musculo-skeletal (Superficial)					·								
Intravascular	ļ												
Other (Ob/GYN)							····	<u> </u>					
Other (Urology)													
Cardiac Adult													
Cardiac Pediatric													
Intravascular(Cardiac)								<u> </u>					
Trans-esoph.(Cardiac)													
Intra-cardiac				· · · · · · · · · · · · · · · · · · ·				l					
Other (specify)													
Peripheral vessel	N	Ν	N		N	N	Note 1	Notes 2, 4					
Other (specify)								· · · · · ·					
	Specific (TRACKS 1 & 3) Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph (non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Other (Urology) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel	Specific (TRACKS 1 & 3) Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Other (Urology) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel N	Specific (TRACKS 1 & 3) Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) N Nonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Other (Urology) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel N N	Specific (TRACKS 1 & 3) Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) N N N Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Other (Urology) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel N N N	Specific (TRACKS 1 & 3) Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-rectal Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Other (Urology) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel N N N	Specific (TRACKS 1 & 3) B M PWD CWD Doppler Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) N N N N N Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph (non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Other (Urology) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel N N N N	Specific (TRACKS 1 & 3) B M PWD CWD Doppler Power (Amplitude) Doppler Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) N N N N N N N Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-vaginal Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Other (Urology) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intravascular(Cardiac) Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel N N N N N N N N	Specific (TRACKS 1 & 3)					

Letihiletai	renpheral vessel	I IV	1.4	[N	IN	[N	i note i	Notes 2	
Vessel	Other (specify)								
N = new indication;	P = pro	viously	cleare	d by FDA			E = added under	this appendix	
Note 1: Other Co	mbined includes: B/M; E	3/PWD	, B/T	HI (The	feature does not use o				
	r; B/Color Doppler/PWI						,		
Note 2: Tissue H	armonic Imaging		No	te 3: TD	Note 4: 3D		Note 5: 4	4D	
Note 6: Small Or	gan: breast, thyroid, teste	s							
Prescription Use X AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)									
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Division of Radiological Devices

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Indications For Use

Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: L742 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation										
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CMD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify				
Ophthalmic	Ophthalmic												
Fetal Imaging&	Fetal												
Other	Abdominal												
	Intra-operative Specify							-	 				
	Intra-operative Neuro						· · · · · · · · · · · · · · · · · · ·						
	Laparoscopic	T											
	Pediatric												
	Small Organ (specify)	N	N	N		N	Ň	Note 1	Notes 2, 4				
	Neonatal Cephalic	\top							,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				
	Adult Cephalic												
	Trans-rectal	1	П										
	Trans-vaginal	+			· · · · · · · · · · · · · · · · · · ·				 				
	Trans-urethral	1							· · · · · · · · · · · · · · · ·				
	Trans-esoph.(non-Card)	+							 				
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2, 4				
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2, 4				
	Intravascular							· · · · · · · · · · · · · · · · · · ·					
	Other (Ob/GYN)												
	Other (Urology)												
Cardiac	Cardiac Adult												
	Cardiac Pediatric												
	Intravascular(Cardiac)						<u> </u>	· · · · · · · · · · · · · · · · · · ·					
	Trans-esoph.(Cardiac)												
	Intra-cardiac								†				
	Other (specify)												
Peripheral	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2, 4				
Vessel	Other (specify)												

N = new indication;	P = previously cleared by FDA;	E34.4 4.2
Note 1: Other Combined inc	cludes: B/M; B/PWD; B/THI (The feature does r Doppler/PWD; B/Power Doppler/PWD	E = added under this appendent use contrast agents); M/Color M; B/Color
Note 2: Tissue Harmonic In Note 6: Small Organ: breast		4: 3D Note 5: 4D
Prescription Use X (Part 21 CFR 801 Subpart I	AND/OR	Over-The-Counter Use(21 CFR 807 Subpart C)
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Office of In Vitro Diagnostic Device Evaluation and Safety

Indications For Use

~ KIN2642

Transducer: MPTEE Multi-plane Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application					Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify				
Ophthalmic	Ophthalmic			· · · · · · · · · · · · · · · · · · ·									
Fetal Imaging&	Fetal					<u></u>							
Other	Abdominal												
	Intra-operative Specify						<u> </u>						
	Intra-operative Neuro	1							· · · · · · · · · · · · · · · · · · ·				
	Laparoscopic						· · · · · · · · · · · · · · · · · · ·						
	Pediatric												
	Small Organ (specify)	1											
	Neonatal Cephalic												
	Adult Cephalic	1					· ·						
	Trans-rectal	1				·							
	Trans-vaginal	+											
	Trans-urethral	+											
	Trans-esoph.(non-Card)												
	Musculo-skeletal	-											
	(Conventional)												
	Musculo-skeletal (Superficial)												
	Intravascular	1											
	Other (Ob/GYN)												
	Other (Urology)												
Cardiac	Cardiac Adult												
	Cardiac Pediatric	1											
	Intravascular(Cardiac)												
	Trans-esoph.(Cardiac)	N	N	N	N	N	N	Note 1	Notes 2,3, 4				
	Intra-cardiac							11010 1	140103 2,5,				
	Other (specify)	1											
Peripheral	Peripheral vessel		•										
Vessel	Other (specify)	\sqcap											
N = new indication	n: P = previ	ously c	leared	by FDA;		l		added under this:	ennendiy				

N = new indication;	P = previously cleared by FDA;		E = added under this appendix		
Note 1: Other Combined inclu	ides: B/M; B/PWD; B/THI (The featur	e does not use contr	ast agents); M/Color M; B/Color		
Doppler; B/Color D	oppler/PWD; B/Power Doppler/PWD		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Note 2: Tissue Harmonic Ima	ging Note 3: TDI	Note 4: 3D	Note 5: 4D		
Note 6: Small Organ: breast, t	hyroid, testes				
Prescription UseX	AND/OR		Over-The-Counter Use		
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)		
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Office of In Vitro Diagnostic Device Evaluation and Safety

Indications For Use

Kinneal

Transducer: MPTEE mini Multi-plane Array Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application						Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthaimic								
Fetal Imaging &	Fetal	1				· · · · · · · · · · · · · · · · · · ·			<u> </u>
Other	Abdominal								
	Intra-operative Specify								······································
	Intra-operative Neuro								
	Laparoscopic	1							· · · · · · · · · · · · · · · · · · ·
	Pediatric	 				·			
	Small Organ (specify)								·
	Neonatal Cephalic								
	Adult Cephalic	1							
	Trans-rectal					·		-	
	Trans-vaginal	+				·			· · · · · · · · · · · · · · · · · · ·
	Trans-urethral	 					· · · · · · · · · · · · · · · · · · ·		
	Trans-esoph.(non-Card)	+					-		
•	Musculo-skeletal	+							· · · · · · · · · · · · · · · · · · ·
	(Conventional)								
	Musculo-skeletal (Superficial)								<u>, , , , , , , , , , , , , , , , , , , </u>
	Intravascular	1							····
	Other (Ob/GYN)	1					·- · · · · · · · · · · · · · · · · · ·		
	Other (Urology)		\Box						·· · · · · · · · · · · · · · · · · · ·
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	N	N	N	N	N	N	Note 1	Notes 2,3, 4
	Intra-cardiac								
	Other (specify)			1				-	
Peripheral	Peripheral vessel							· · · · · · · · · · · · · · · · · · ·	·
Vessel	Other (specify)						· · · · · · · · · · · · · · · · · · ·		

			1 1	ľ		1 1				
/essel	Other (specify)				1		* 		-	
[*] Doppl	ombined includes: er, B/Color Doppl	B/M; B/P er/PWD; I	WD; B	red by FDA THI (The r Doppler	e featu	re does not use co	E=ntrast agents); N	= added under the M/Color M; B	is appendix Color	
	Harmonic Imaging organ: breast, thyro		N	lote 3: TE	I	Note 4: 3D		Note 5: 4E)	
Prescription Use Part 21 CFR 80		•	AND/OR				Over-The-Counter Use(21 CFR 807 Subpart C)			
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